CDC

CENTERS FOR DISEASE CONTROL

# CLIA'88

# Focus on Clinic and Office Laboratories

QY
25
C641f
1988

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control

If you are directing or supervising a clinic or physician's office laboratory (POL) that will be regulated by the Federal government for the first time, this brochure will introduce you to the new regulatory requirements. Some of the most common questions are answered and you can learn how to obtain further information about how the regulations will apply to your unique laboratory situation.

**Q. What is CLIA, and what will it do for me?**

A. In 1988, several media reports focused public and Congressional attention on deficiencies in the quality of services provided by some of the Nation's clinical laboratories. The Clinical Laboratory Improvement Amendments of 1988, or CLIA, resulted from Congressional examination of the situation, including investigation of testing performed in POLs. CLIA sets standards designed to improve quality in all laboratory testing and includes specifications for quality control, quality assurance, patient test management, personnel and proficiency testing.

In determining the final regulations to implement CLIA, the Department of Health and Human Services considered thousands of public comments to the proposed regulations and consulted with many clinicians and others who have clinical laboratory testing expertise. The regulations set minimum standards for laboratory practice and quality. When your laboratory satisfies CLIA regulatory requirements, you as well as your patients can have greater confidence in the quality and reliability of your laboratory results.

**Q. Since I perform only a few simple tests in my office, do CLIA regulations apply to my practice?**

A. Yes. CLIA regulations concern all laboratory testing used for the assessment of human health or the diagnosis, prevention, or treatment of disease. CLIA applies to every laboratory and testing site in the United States, even if only a few basic tests are performed as part of physical examinations.

Some simple tests are waived from specific CLIA requirements. If your laboratory performs only these tests, you need to obtain a certificate of waiver to show that your laboratory is exempt from specific CLIA requirements.

**Q. If I do only dipstick urinalyses and spun hematocrits on my patients, is my laboratory eligible for a waiver?**

A. Yes. These procedures are among the eight tests exempt from specific CLIA standards. The eight tests are as follows:

- Dipstick or tablet urinalysis (nonautomated)
- Fecal occult blood
- Ovulation test using visual color comparison
- Urine pregnancy test using visual color comparison
- Erythrocyte sedimentation rate
- Hemoglobin by copper sulfate method
- Spun microhematocrit
- Blood glucose using certain devices cleared by the Food and Drug Administration (FDA) specifically for home use

If you perform only the tests on this list and no others, you must obtain a certificate of waiver. While no specific CLIA regulations apply to the performance of these tests, you are expected to follow the test manufacturer's instructions. Laboratories with certificates of waiver will not be inspected routinely; however, they may be inspected as part of complaint investigations and on a random basis to determine whether only the waived tests are being performed.

**Q. What if my laboratory performs tests not on the list of waived procedures?**

A. All tests not listed as waived are divided into one of two categories, **moderate complexity** or **high complexity**, based on the complexity of the testing procedure. For both of these categories the CLIA regulations list specific requirements for proficiency testing, patient test management, quality control, quality assurance, personnel, and inspections. Most testing performed in POLs or which is essential for immediate patient care is categorized as moderate complexity, unless it is waived. More than 40 general methodologies which include several thousand specific test systems, assays or examinations are listed in this category. Some examples of moderate complexity tests are microscopic analysis of urinary sediment, throat cultures, Gram stains, and hematology and chemistry tests conducted on fully automated instruments that do not require operator intervention during the analytic process.

**Q. How can I determine whether a test my laboratory performs is classified as moderate or high complexity?**

A. A preliminary listing of several thousand test systems, assays, and examinations in both the moderate and high complexity categories was published in the Federal Register on the same day the CLIA regulations were published. A complete list will be published within 6 months of this date in the Federal Register. Thereafter, updates will be published periodically. See page 8 of this brochure for instructions on obtaining a copy of the Federal Register.

**Q. What are the major differences between the requirements for laboratories performing tests of moderate and high complexity?**

A. The major differences in requirements between moderate and high complexity testing concern quality control (QC) and personnel standards. Laboratories performing high complexity testing must completely meet the QC requirements by the effective date of the regulations, whereas some QC standards for moderate complexity testing are being implemented in stages.

Personnel standards for high complexity testing are more rigorous than those for moderate complexity testing since the testing itself is more complicated. In general, personnel conducting high complexity testing will need more education and experience than those doing moderate complexity testing.

**Q. If my laboratory conducts only testing of moderate complexity, must I hire a pathologist as laboratory director?**

A. No. The personnel regulations identify the functional capabilities needed by your laboratory employees as well as the minimum qualifications for individuals who fill the positions. Laboratories conducting moderate complexity testing must have employees who qualify and can perform the functions described in the regulations as the responsibilities for the following:

- Laboratory director
- Clinical consultant
- Technical consultant
- Testing personnel

It is possible for the same individual, if qualified, to perform more than one of these functions; he or she may even fill all four positions.

The **laboratory director** is responsible for the overall operation and administration of the laboratory. To qualify as director, an individual who is a doctor of medicine or osteopathy must either be a pathologist or have had at least 1 year of experience directing or supervising moderate or high complexity laboratory testing. If you are an MD or DO and do not have this experience, you can continue to serve as a laboratory director by earning at least 20 continuing medical education (CME) hours in laboratory practice by one year after the publication date of the regulations. You can also qualify as director if you have obtained laboratory training during your medical residency equivalent to 20 CME hours. Individuals who have doctoral, master's, or bachelor's degrees in one of the biological, chemical, physical, or clinical laboratory sciences can also qualify as laboratory directors if they have the appropriate training and experience. In addition, if you were qualified on the date the regulations were published under state law to direct a laboratory in the state in which your laboratory is located, you remain qualified.

**Q. What are the required qualifications and functions of the clinical and technical consultant?**

A. The **clinical consultant** must be either a physician or a board-certified doctoral level scientist. He or she serves as the liaison between the laboratory and its clients in reporting and interpreting results.

The **technical consultant** is responsible for the technical and scientific oversight of the laboratory. The employee who performs this function must have a medical degree or an undergraduate or advanced degree in one of the sciences and 1 or 2 years of specific laboratory training or experience in the laboratory specialty of the consultation.

In a POL, a physician would most likely serve as the clinical consultant and may also serve as the technical consultant, if he or she has at least 1 year of training or experience in the appropriate area of laboratory service. For example, if you are a physician and you or your staff perform several hematology, chemistry, and microbiology tests in your office, you must have either 1 year of experience in conducting these tests in your office or a total of 1 year of training or experience in hematology, chemistry, and microbiology to qualify as technical consultant. If you or someone else in your office laboratory cannot

meet the requirements, you must hire a qualified person(s) as a consultant to perform the technical functions until you or a staff member acquire the necessary experience. The technical consultant must be available on an as-needed basis and is responsible for selecting test methods and establishing their performance characteristics, implementing a QC program, enrolling in and monitoring proficiency testing, resolving technical problems, evaluating the competency and performance of testing personnel, and providing training.

*Q.* **Can the nurse in my office continue to perform the laboratory testing?**

*A.* In most cases, yes. The **testing personnel** for moderate complexity testing must have, at minimum, a high school diploma and documentation of satisfactory completion of training appropriate to the testing performed in your office or clinic laboratory. This training may have been obtained either formally or informally on the job. If you are performing high complexity testing in your laboratory, a nurse may not qualify unless he or she can meet specific education requirements.

*Q.* **Does my laboratory have to change the way we are performing laboratory tests?**

*A.* Perhaps. If you have not been performing adequate QC procedures and your laboratory conducts tests not categorized as waived, you will need to begin performing routine QC procedures and documenting their results. During the first 2 years of CLIA implementation, if you are performing moderate complexity tests using systems cleared by the FDA for in vitro diagnostic use, your laboratory must, at minimum, follow the manufacturer's instructions, perform and document calibration procedures at least once every 6 months, run two levels of controls daily, perform applicable specialty and subspecialty QC procedures, prepare a procedure manual, and perform and document remedial action taken when errors are identified.

If your laboratory performs either moderate complexity testing using systems cleared for in vitro diagnostic use that you have modified or high complexity testing, you must follow all applicable QC rules listed in the regulations.

During the first 2 years of implementation, the FDA will begin clearing tests as meeting CLIA QC requirements. This means that after mid-1994, you will meet most of the CLIA QC requirements by following the test manufacturer's instructions when using systems cleared in this manner.

**Q. Do I have to change the way I'm using laboratory tests in my practice?**

A. No. CLIA does not apply to the use of laboratory test results or to the medical decision-making process. It focuses specifically on standards for laboratory test performance.

**Q. What is proficiency testing and how does it relate to my office laboratory?**

A. Proficiency testing (PT), mandated by CLIA, is an external evaluation of the quality of a laboratory's performance. When your laboratory enrolls in an approved PT program, you will receive specimens to evaluate in the same way that you routinely test patient specimens. In general, PT programs will provide five samples for each analyte or test 3 times per year (i.e., 3 testing events per year). After your laboratory has tested the samples, you must return the results to the PT program for grading, where your laboratory's results will be compared with the consensus answer from referee laboratories for the same specimens. With a few exceptions, the passing score is 80%.

PT is being phased in gradually to allow laboratories and PT program providers sufficient time to meet the requirements. Newly regulated laboratories, including most POLs, must enroll in a PT program during 1993 to begin participating in 1994. By that time your laboratory must participate in programs for each specialty, subspecialty, analyte, or test for which it is certified and for which PT is required.

**Q. What happens if my laboratory fails PT?**

A. If your laboratory receives a failing score for an analyte, test, subspecialty or specialty, you or your laboratory personnel must take necessary actions to find, correct, and document any problems in the testing performance. If a laboratory fails two consecutive or two out of three PT events, the laboratory will be subject to penalties. Newly regulated laboratories, however, will not be penalized for PT failures until 1995, although they will be expected to correct whatever problems resulted in failure. This means your laboratory will have 1 year to learn how PT works before penalties for failure will be incurred. If failure is so severe as to suggest that patient health and safety is jeopardized, however, immediate action will be taken.

**Q. Will my office laboratory be inspected and, if so, what will the inspection involve?**

A. If your laboratory conducts nonwaived testing, an inspection will occur within the first 2 years after you register with the Health Care Financing Administration (HCFA). During an inspection you or your laboratory personnel may be asked to perform procedures, show an inspector all of the areas of the laboratory, and provide requested documentation. After your laboratory is certified, inspections will be conducted every 2 years or, if necessary, as part of a complaint investigation. Inspections may occur without prior notice.

**Q. How do I sign up?**

A. First, you must obtain either a certificate of waiver or, if your laboratory performs nonwaived testing, a registration certificate. If you have not already been contacted by HCFA about CLIA you may obtain information and an application from the HCFA office in your region. The regional offices are listed on the last 2 pages of this brochure. Registration certificates are valid for a maximum of 2 years or until such time as an inspection can be conducted to determine program compliance, whichever is shorter. Certificates are issued to laboratories complying with the Department program and certificates of accreditation to those complying with Department-approved, private, nonprofit accreditation programs. In addition, in states with Federally approved licensure programs a laboratory may obtain a state license in lieu of a certificate or certificate of accreditation. If your laboratory is located in a state with an approved program and you obtain a state license, you will have only to comply with the state rules, not the Federal CLIA regulations. In choosing which type of certification to seek, you may consider factors such as cost, convenience, professional affiliations, and other considerations beyond the scope of this discussion.

**Q. What costs are involved for laboratories to meet the CLIA regulations?**

A. The major costs to all laboratories involve fees for certification and compliance and enrollment in PT programs. These costs will vary, depending on the amount of testing conducted in the laboratory and on the types of PT programs in which the laboratory enrolls.

Laboratories conducting only waived testing must pay a fee of $100 to obtain a certificate of waiver. Fees for registration certificates for most POLs will range from $100 to $350, depending on testing volume and the number of laboratory specialties for which the laboratory seeks certification. Inspection fees will also be assessed on the basis of volume of testing and types of services. The costs associated with participating in PT will vary by the number of tests for which the laboratory participates and the PT program. In general, PT costs will be lower for laboratories conducting limited testing than for those conducting a large variety of tests in several specialties or subspecialties. Some laboratories may incur additional costs associated with increased QC activities, quality assurance implementation, training for personnel, and hiring of consultants.

*Q.* **How can I obtain more information about the regulations?**

*A.* You can order copies of the Federal Register containing the CLIA standards for laboratories and the preliminary list of tests in the moderate and high complexity categories for a small fee. Send your request to:

Government Printing Office
ATTN: New Orders
P.O. Box 371954
Pittsburgh, PA 15250-7954

Specify the date of the issue that you are requesting (February 28, 1992) and your choice of paper or microfiche format. Enclose a check or money order payable to the Superintendent of Documents. Credit card orders can also be placed by calling the order desk at (202) 783-3238 or by faxing to (202) 512-2250. In addition, you may view and photocopy the Federal Register at most libraries designated as U.S. Government Depository Libraries and at many other public and academic libraries throughout the country. The order desk operator can tell you the location of the nearest U.S. Government Depository Library.

## Regional Offices of the Health Care Financing Administration

**REGION I**
(CT, ME, MA, NH, RI, VT)
Room 1211
JFK Federal Building
Boston, MA 02203
(617) 565-1322

**REGION II**
(NJ, NY, PR, VI)
Room 3821
26 Federal Plaza
New York, NY 10278
(212) 264-1121

**REGION III**
(DE, DC, MD, PA, VA, WV)
3535 Market Street
P.O. Box 7760
Philadelphia, PA 19101
(215) 596-6571

**REGION IV**
(AL, FL, GA, KY, MS, NC, SC, TN)
Suite 601
101 Marietta Tower
Atlanta, GA 30323
(404) 841-2361

**REGION V**
(IL, IN, MI, OH, WI)
105 West Adams Street
15th Floor
Chicago, IL 60603-6201
(312) 353-9804

**REGION VI**
(AR, LA, NM, OK, TX)
Room 1935
1200 Main Tower Building
Dallas, TX 75202
(214) 767-6301

**REGION VII**
(IA, KS, MO, NE)
New Federal Office Building
601 East 12th Street, Room 242
Kansas City, MO 64106
(816) 426-2408

**REGION VIII**
(CO, MT, ND, SD, UT, WY)
Federal Building
1961 Stout Street, Room 1185
Denver, CO 80294
(303) 844-4721

**REGION IX**
(AZ, CA, HI, NV, US Pacific Islands)
75 Hawthorne Street
4th Floor
San Francisco, CA 94105
(415) 744-3679

**REGION X**
(AK, ID, OR, WA)
2201 Sixth Avenue
Mail Stop RX-42
Seattle, WA 98121
(206) 553-0511

REGION VII
(IA, KS, MO, NE)
Federal Office Building
601 East 12th Street, Room 242
Kansas City, MO 64106
(816) 426-2928

REGION VIII
(CO, MT, ND, SD, UT, WY)
Federal Building
1961 Stout Street, Room 1185
Denver, CO 80294
(303) 844-4731

REGION IX
(AZ, CA, HI, NV, US Pacific Islands)
75 Hawthorne Street
San Francisco, CA 94105
(415) 744-3679

REGION X
(AK, ID, OR, WA)
2201 Sixth Avenue
Mail Stop RX-43
Seattle, WA 98121
(206) 553-0211